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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/518,554

03/03/2000

Jacob Vroman

AIMPORT.011A

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05/02/2006

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,554

Applicant(s)

VROMAN, JACOB

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 24, 27-32 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 27-32 and 36-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action and Applicant's Arguments/Remarks, both filed 02/13/06 is acknowledged.

Claims 23, 24, 27-32 and 36-45 are pending in this action. Claims 1-22, 25, 26 and 33-35 have previously been cancelled. Claims 23, 24, 27-32 and 36-45 remain rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23, 24, 27-32 and 36-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-45 of copending Application No. 09/562,778 in view of Siddiqui (US Pat. No. 6,146,664) ('664 Patent).

The instant invention is drawn to a method of providing one or more of the following treatments to a mammal in need of such treatment: UV protection, decrease or alleviation of wrinkles, or stimulating collagen production in a mammal, said method comprising: identifying a mammal in need of such treatment, and topically applying to said mammal a composition comprising at least 30% L-ascorbic acid, by weight, micronized in an oil selected from caprylic triglycerides, capric triglycerides, isostearic triglycerides, adipic triglycerides, propylene glycol myristyl acetate, lanolin oil, polybutene, isopropyl palmitate, isopropyl myristate, diethyl sebacate, diisopropyl adipate, hexadecyl stearate, cetyl oleate, oleyl alcohol, hexadecyl alcohol, wheat germ oil, vegetable oils such as castor oil, corn oil, cottonseed oil, olive oil, palm oil, coconut oil, palm kernel oil, canola oil, sunflower oil, safflower oil, meadow foam oil, jojoba oil, hydrogenated vegetable oils and mineral oil, a non-aqueous carrier selected from esters, amides, ethoxylated fats, mineral oil, petrolatum, vegetable oils, animal fats, triglycerides, polyols including glycerol, propylene glycol, glycerin and sorbitol, and an exfoliant, wherein the mean particle size of the L-ascorbic acid is no greater than approximately 5 μm .

The copending '778 application is drawn to a composition for topical use comprising greater than approximately 25% micronized L-ascorbic acid, by weight, a non-aqueous carrier, and an exfoliant, wherein the exfoliant is an enzyme. The copending '778 application is also drawn to a method for preparing a topical L-ascorbic acid composition comprising micronizing ascorbic acid powder in an oil, and adding an exfoliant wherein the resultant composition

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comprises greater than approximately 25% L-ascorbic acid by weight and wherein the exfoliant is an enzyme.

Similar subject matter has been claimed in each of the applications. While the copending '778 application does not set forth the particular use of the ascorbic acid composition, such as for use in UV protection, decrease or alleviation of wrinkles, or stimulating collagen production, as claimed in the instant application, it is the position of the Examiner that it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made to formulate a topical ascorbic acid-containing formulation in combination with additional components (*i.e.* exfoliants) for use in the effective treatment of skin conditions, particularly for providing UV protection, alleviation of wrinkles and/or increasing collagen production.

The secondary reference of Siddiqui ('664 Patent) is relied upon for the teaching of stable topical ascorbic acid compositions wherein ascorbic acid provides a high degree of bioavailability and effectiveness for topical applications to reduce wrinkles and increase collagen growth and elasticity (see Abstract). Also see Table 5 at column 7, wherein the data in Table 5 clearly demonstrates that the ascorbic acid product is effective at improving skin elasticity and the appearance of fine lines and wrinkles. The data represents a dramatic improvement in the amounts of collagen in the skin that results in increased skin elasticity and a simultaneous improvement in skin texture (*i.e.*, reduction in fine lines and wrinkles).

Therefore, it is the position of the Examiner, that given the teachings of Siddiqui ('664) delineated above, it would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate stable, topical ascorbic acid compositions for use in effectively reducing wrinkles, improving skin appearance/texture and increasing collagen

productivity to a person in need thereof. The expected result would be an optimally enhanced method for the treatment of skin conditions in a human.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 02/13/06 have been fully considered but were not found to be persuasive. Applicant argued regarding the non-statutory Double Patenting rejection stating, "If this provisional double patenting rejection is the only remaining rejection in the application, Applicants request that the Examiner withdraw the rejection and allow the application to issue as a patent (See MPEP §804(I)(B)). Applicants will then consider filing a Terminal Disclaimer or take any other action deemed necessary in the copending application."

Applicant's arguments have been fully considered but were not persuasive. The non-statutory Double Patenting of claims 23, 24, 27-32 and 36-45 over claims 26-45 of copending Application No. 09/562,778 in view of Siddiqui (US Pat. No. 6,146,664) ('664 Patent) has been maintained and is deemed proper, since there still remains conflicting claims in more than one application. The filing of a Terminal Disclaimer may be used to overcome this provisional double patenting rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

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April 28, 2006

Humera N. Sheikh
TC-1600

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